9200/1645

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Tracey Simmons
Printed name of person mailing correspondence

Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	Virginia A. Portner
Filed:	June 21, 2000	Customer No.:	21559
Title:	NOVEL ORGANISM ASSOCIATED WITH NONGONOCOCCAL URETHRITIS		

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION TO WITHDRAW NOTICE OF ABANDONMENT

Under 37 C.F.R. §§ 1.8(b) and 1.181, Applicant hereby petitions to have the Notice of Abandonment that was mailed in connection with the above-captioned case on May 18, 2004 withdrawn. A copy of the Notice is enclosed. According to the Notice, the application was abandoned under 37 C.F.R. § 1.135 for applicant's failure to reply to an Office action that was mailed on October 29, 2003. However, as explained below, a reply was timely filed on April 29, 2004.

The undersigned, applicant's attorney of record, first became aware of the abandonment on May 20, 2004, upon receipt of the Notice of Abandonment and submits

that this petition to withdraw the Notice is being promptly submitted as required by 37 C.F.R. § 1.8(b)(1).

The following documents are submitted under 37 C.F.R. § 1.8(b)(2) as proof that a reply was timely filed on April 29, 2004:

1. A copy of the reply, including an executed certificate of mailing signed by Tracey Simmons on April 29, 2004.

2. A copy of the Petition for Extension of Time, including an executed certificate of mailing signed by Tracey Simmons on April 29, 2004, which extended the period for replying to the Office Action for three months, to and including April 29, 2004;

3. A copy of a check dated April 28, 2004 and postcard dated April 29, 2004 that were included with the reply and Petition for Extension.

4. A copy of the postcard that was stamped as having been received by the PTO Mailroom on May 3, 2004.

Also enclosed are original signed declarations under 37 C.F.R. § 1.8(b)(3) by:

1. Paul T. Clark, attesting on the basis of personal knowledge that the above documents were timely filed on April 29, 2004.

2. Tracey Simmons, attesting on the basis of personal knowledge that the above documents were timely filed on April 29, 2004.

3. Elvis De La Cruz, attesting on the basis of personal knowledge to the mail procedures in effect on April 29, 2004.

Applicant submits that the reply was timely filed and requests that the Notice of Abandonment be withdrawn.

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: May 25, 2004

Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

UNITED STATES PATENT AND TRADEMARK OFFICE

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/598,604	06/21/2000	Barbara B. Lambl	50172/002001	7546

21559 7590 05/18/2004

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

EXAMINER	
PORTNER, VIRGINIA ALLEN	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/18/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

ACTION DUE With Abandonment
DUE DATE 7.18.04
INITIALS MN

ACTION DUE Ret to Revive
DUE DATE 5.18.05
INITIALS MN

Notice of Abandonment

Application No.	Applicant(s)	
09/598,604	LAMBI, BARBARA B	TECH CENTER 1600/2900
Examiner	**Art Unit**	
Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

This application is abandoned in view of:

1. ☒ Applicant's failure to timely file a proper reply to the Office letter mailed on *29 October 2003*.
   (a) ☐ A reply was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply (including a total extension of time of _____ month(s)) which expired on _____.
   (b) ☐ A proposed reply was received on _____, but it does not constitute a proper reply under 37 CFR 1.113 (a) to the final rejection.
   (A proper reply under 37 CFR 1.113 to a final rejection consists only of: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114).
   (c) ☒ A reply was received on *5/2003* but it does not constitute a proper reply, or a bona fide attempt at a proper reply, to the non-final rejection. See 37 CFR 1.85(a) and 1.111. (See explanation in box 7 below).
   (d) ☐ No reply has been received.

2. ☐ Applicant's failure to timely pay the required issue fee and publication fee, if applicable, within the statutory period of three months from the mailing date of the Notice of Allowance (PTOL-85).
   (a) ☐ The issue fee and publication fee, if applicable, was received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the statutory period for payment of the issue fee (and publication fee) set in the Notice of Allowance (PTOL-85).
   (b) ☐ The submitted fee of $_____ is insufficient. A balance of $_____ is due.
   The issue fee required by 37 CFR 1.18 is $_____. The publication fee, if required by 37 CFR 1.18(d), is $_____.
   (c) ☐ The issue fee and publication fee, if applicable, has not been received.

3. ☐ Applicant's failure to timely file corrected drawings as required by, and within the three-month period set in, the Notice of Allowability (PTO-37).
   (a) ☐ Proposed corrected drawings were received on _____ (with a Certificate of Mailing or Transmission dated _____), which is after the expiration of the period for reply.
   (b) ☐ No corrected drawings have been received.

4. ☐ The letter of express abandonment which is signed by the attorney or agent of record, the assignee of the entire interest, or all of the applicants.

5. ☐ The letter of express abandonment which is signed by an attorney or agent (acting in a representative capacity under 37 CFR 1.34(a)) upon the filing of a continuing application.

6. ☐ The decision by the Board of Patent Appeals and Interference rendered on _____ and because the period for seeking court review of the decision has expired and there are no allowed claims.

7. ☐ The reason(s) below:

L. T. Smith

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Petitions to revive under 37 CFR 1.137(a) or (b), or requests to withdraw the holding of abandonment under 37 CFR 1.181, should be promptly filed to minimize any negative effects on patent term.

JUN 1 2004

PATENT
ATTORNEY DOCKET NO. 50172/002001

Certificate of Mailing: Date of Deposit: May 25, 2004

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Tracey Simmons
Printed name of person mailing correspondence

Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	Virginia A. Portner
Filed:	June 21, 2000	Customer No.:	21559
Title:	NOVEL ORGANISM ASSOCIATED WITH NONGONOCOCCAL URETHRITIS		

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF PAUL T. CLARK

I, Paul T. Clark, declare as follows:

I am a partner in the law firm of Clark & Elbing LLP and an attorney of record in the above-captioned case.

I first became aware of the abandonment of the above-captioned application on May 20, 2004, upon receipt of a Notice of Abandonment. According to the Notice, the application was abandoned under 37 C.F.R. § 1.135 for applicant's failure to reply to an Office action that was mailed on October 29, 2003. However, a reply was timely filed on

April 29, 2004. I submit that the accompanying petition to withdraw the Notice is being promptly submitted as required by 37 C.F.R. § 1.8 (b) (1).

All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 5-25, 2004

Paul T. Clark

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

PATENT
ATTORNEY DOCKET NO. 50172/002001

Certificate of Mailing: Date of Deposit: May 25, 2004

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Tracey Simmons
Printed name of person mailing correspondence

Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	Virginia A. Portner
Filed:	June 21, 2000	Customer No.:	21559
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Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF TRACEY SIMMONS
ATTESTING TO FILING DATE UNDER 37 C.F.R. § 1.8(b)(3)
FOR CORRESPONDENCE MAILED BUT NOT RECEIVED BY THE PTO

1. I, Tracey Simmons, am an employee of Clark & Elbing LLP.

2. I signed the certificate of mailing on the Reply to Examiner's Action and Petition for Extension of Time mailed on April 29, 2004, copies of which are enclosed.

3. I hereby attest that I had reasonable basis to believe the correspondence would be mailed on that date.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further

that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 5/25/04

Tracey Simmons

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

PATENT
ATTORNEY DOCKET NO. 50172/002001

Certificate of Mailing: Date of Deposit: May 25, 2004

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Tracey Simmons
Printed name of person mailing correspondence

Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	Virginia A. Portner
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Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION OF ELVIS DE LA CRUZ

I, Elvis De La Cruz, declare as follows:

I am employed by Clark & Elbing LLP. On April 29, 2004, one of my responsibilities was to ensure the delivery of firm mail to the United States Postal Service.

The Clark & Elbing LLP mailroom procedures that I and all other employees follow require that all mail to be taken to the Post Office be left in a specially designated box in the mailroom. The procedure in place on April 29, 2004 required that, after the

close of business each day, I or another designated employee check the box for mail and deliver it by hand to an employee of the United States Postal Service's General Mail Facility on Dorchester Avenue in Boston.

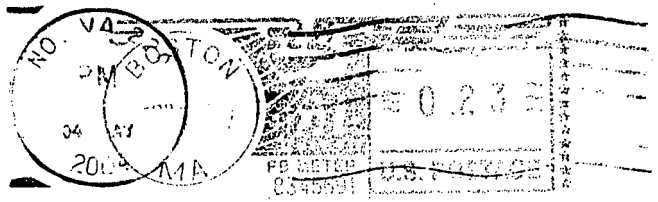
All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 5/25/04

Elvis De La Cruz

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045



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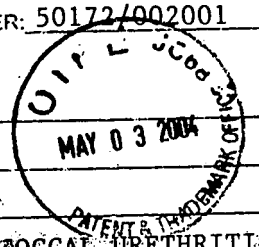

Applicant/Patentee: Barbara B. Lambl

Serial/Patent Number: 09/598,604

Filed/Issued: June 21, 2000

Title: NOVEL ORGANISM ASSOCIATED WITH NONGONOCOCCAL URETHRITIS

☐ Transmittal Letter	Pages:_____	☐ Declaration & POA	Pages:_____
☐ Notice to File Missing Parts	Pages:_____	☐ Assignment & Cover Sheet	Pages:_____
☐ Reply to Missing Parts	Pages:_____	☐ Change of Address	Pages:_____
☒ Reply to Office Action	Pages: 24	☐ Preliminary Amendment	Pages:_____
☒ Petition for Extension	Pages: 1	☐ IDS	Pages:_____
☐ Notice of Appeal	Pages:_____	☐ Form PTO-1449	Pages:_____
☐ Appeal Brief	Pages:_____	☐ Cited References	Number:_____
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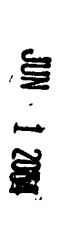
☐ Other_____			Pages:_____
☐ Other_____			Pages:_____

Atty/Secy: PTC/RTA/tms Client/Matter Name: Lambl/Urethritis Date: 04/29/04



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PATENT
ATTORNEY DOCKET NUMBER: 50172/002001

The U.S. PTO date stamp sets forth the date of receipt of:

Applicant/Patentee: Barbara B. Lambl

Serial/Patent Number: 09/598,604

Filed/Issued: June 21, 2000

Title: NOVEL ORGANISM ASSOCIATED WITH NONGONOCOCCAL URETHRITIS

☐ Transmittal Letter	Pages:	☐ Declaration & POA	Pages:
☐ Notice to File Missing Parts	Pages:	☐ Assignment & Cover Sheet	Pages:
☐ Reply to Missing Parts	Pages:	☐ Change of Address	Pages:
☒ Reply to Office Action	Pages: 24	☐ Preliminary Amendment	Pages:
☒ Petition for Extension	Pages: 2	☐ IDS	Pages:
☐ Notice of Appeal	Pages:	☐ Form PTO-1449	Pages:
☐ Appeal Brief	Pages:	☐ Cited References	Number:
☐ Drawings Formal/Informal	Pages:	☐ Sequence Listing	Pages:
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Tracey Simmons
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Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	V. Portner
Filed:	June 21, 2000	Customer No.:	21559
Title:	NOVEL ORGANISM ASSOCIATED WITH NONGONOCOCCAL URETHRITIS		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PETITION FOR EXTENSION OF TIME

Pursuant to 37 C.F.R. § 1.136, Applicant hereby petitions that the period for replying to the Office action that was mailed in connection with the above-captioned application on October 29, 2003 be extended for three months, to and including April 29, 2004.

Enclosed is a check for $475.00 for the fee required by 37 C.F.R. § 1.17(a).

If there are any other charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: April 29, 2004

Paul T. Clark
Reg. No. 30,162

Clark & Elbing LLP
101 Federal Street
Boston, MA 02110
Telephone: 617-428-0200
Facsimile: 617-428-7045

PATENT
ATTORNEY DOCKET NO. 50172/002001

Certificate of Mailing: Date of Deposit: April 29, 2004

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Tracey Simmons
Printed name of person mailing correspondence

Tracey Simmons
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Barbara B. Lambl	Art Unit:	1645
Serial No.:	09/598,604	Examiner:	V. Portner
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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

REPLY TO EXAMINER'S ACTION

In reply to the Office action that was mailed in connection with the above-captioned patent application on October 29, 2003, Applicant submits the following amendment and remarks.

AMENDMENT TO THE CLAIMS

This listing of claims will replace all prior versions of claims in the application:

Listing of Claims:

1. (Currently Amended) A biologically pure culture of a single-celled organism, Spiky Rotating Cells (SPR), wherein said organism causes ~~a~~ disease in humans and comprises the following biological characteristics ~~has~~: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections; (iv)~~ a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) periodic ~~colonial~~ clustering behavior to form colonies; and (vii) existence ~~exists~~ in an extracellular environment.

2-4 (Cancelled)

5. (Currently Amended) A method of diagnosing an SPR infection in a human patient, said method comprising the steps of:

a) obtaining a sample from said patient; and

b) testing said sample for the presence of an organism that causes ~~a~~ disease in humans, said organism having the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections; (iv)~~ a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) periodic ~~colonial~~

clustering behavior to form colonies; and (vii) existence ~~exists~~ in an extracellular environment; wherein the presence of said organism indicates an SPR infection.

6. (Previously Presented) The method of claim 5, wherein said method further comprises, after step a), testing the pH of said sample, wherein a pH greater than 6.0 is further indicative of the presence of said SPR infection.

7. (Previously Presented) The method of claim 5, wherein said patient is a male, and wherein step a) comprises obtaining said sample from the urethra of said male patient, wherein said sample comprises a secretion found in the urethra of said male patient.

8. (Cancelled)

9. (Previously Presented) The method of claim 5, wherein step b) comprises admixing said sample with saline and examining said sample by microscopy, wherein said SPR infection is confirmed by the presence of an organism comprising said biological characteristics.

10. (Previously Presented) The method of claim 5, wherein said patient is a female, and wherein step a) comprises obtaining a sample from the vagina of said female patient, wherein said sample comprises a cervico vaginal secretion from said female patient.

11. (Cancelled)

12. (Previously Presented) The method of claim 5, wherein said patient has a skin eruption or lymph node abscess, and wherein the sample of step a) comprises a secretion from said skin eruption or abscess.

13. (Cancelled)

14. (Previously Presented) An instrument for collecting a sample from a male patient, wherein said sample comprises urethral secretions, said instrument comprising:

a) a handle portion; ~~and~~

b) attached to said handle portion, a means for collecting a secretion from the reproductive system of said male patient, wherein said collecting means is sized and shaped for insertion into the distal end of the urethra of said male patient and comprises a loop region with an opening, wherein said loop region is positioned at the end of said device opposite said handle portion; and

c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

15. (Currently Amended) An instrument for collecting a sample from a female patient, wherein said sample comprises cervico vaginal secretions, and detecting the presence of SPR in said secretions, said instrument comprising:

a) a handle portion;

b) attached to said handle portion, a means for collecting cervico vaginal secretions from said female patient, wherein said collecting means comprises a loop region with an opening, wherein said loop region is positioned at the end of said device opposite said handle portion; and

c) a pH sensor positioned adjacent the collecting means, wherein said pH sensor comes into contact with said sample and detects the pH of said sample.

16. (Cancelled)

17. (Currently Amended) A method of treating an SPR infection in a patient, said method comprising:

a) diagnosing said SPR infection, wherein the organism causing said SPR infection causes a disease in humans and comprises the following biological characteristics: (i) provisional classification as a protozoan (ii) a spherical shape measuring approximately 7-8 μm as a solitary single-celled organism; (iii) ~~spiky membrane projections; (iv)~~ a refractile cell membrane; (iv) multiple circumferential spiky projections of the cell membrane; (v) rotatory motility; (vi) periodic ~~colonial~~ clustering behavior to form colonies; and (vii) existence ~~exists~~ in an extracellular environment; and

b) upon obtaining a positive diagnosis in step a), administering to said patient an SPR-inhibiting amount of an anti-SPR agent selected from the group consisting of itraconazole, ofloxacin, and metronidazole.

18. (Cancelled)

19. (Previously Presented) The culture of claim 1, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of other organs.

20. (Previously Presented) The culture of claim 1, wherein said disease is nongonococcal urethritis.

21. (Previously Presented) The culture of claim 1, wherein said organism proliferates in Diamond's media.

22-34 (Cancelled)

35. (Previously Presented) A single-celled organism having accession number ATCC PTA-2129.

36. (Previously Presented) The method of claim 9, wherein said extracellular environment is skin, fluid of the genital tract, or the extracellular fluid of an organ.

37. (Previously Presented) The method of claim 9, wherein said organism proliferates in Diamond's media.

REMARKS

Summary of the Invention

The invention features a biologically pure culture of a newly identified single-celled organism, designated Spiky Rotating Cells (SPR). The invention also features methods for diagnosing an SPR infection, an instrument for collecting a secretion containing SPR and for detecting an SPR infection in the secretion, and methods for treating an SPR infection.

Summary of the Office Action

Claims 1, 5-7, 9, 10, 12, 14-17, 19-21, and 35-37 are pending. Claim 35 is considered allowable. Claim 16 would be allowable if rewritten in independent form. Claims 1 and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. Claims 1, 5-7, 9-12, 16, 17, 19-21, and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. Claims 1, 5, 7, 10, 12, and 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Abou El Seoud et al. (J. Egypt. Soc. Parasitol. 28:263-270, 1998; hereinafter "Abou El Seoud"). Claims 1, 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Monteiro-Leal et al. (Cell Motility and the Cytoskeleton 34:206-214, 1996; hereinafter "Monteiro-Leal"). Claims 5 and 10 are rejected under 35 U.S.C. § 102(b) for anticipation by Andrews et al. (U.S. Patent No. 5,300,491; hereinafter "Andrews"). Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Birthistle et al. (Genitourin Med. 72:445-452, 1996; hereinafter "Birthistle") and Larson (U.S. Patent No. 6,180,136; hereinafter "Larson"). Claims 5, 7, 9, 10, 19-21, and 36-37 are rejected under 35 U.S.C. § 102(a) for anticipation by van der Schee et al. (J. Clin. Micro. 37:4127-4130, 1999; hereinafter "van der Schee"). Claims 5 and 6 are rejected under 35 U.S.C. § 102(e) for anticipation by Kritzman et al. (U.S. Patent No. 5,660,790; hereinafter "Kritzman").

Claim 14 is rejected under 35 U.S.C. § 102(b) for anticipation by Bush et al. (Amer. J. Roentgenology 144:795-799, 1985; hereinafter "Bush"). Finally, claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Nucci (U.S. Patent No. 5,063,930; hereinafter "Nucci") and Hardy (U.S. Patent No. 2,644,879; hereinafter "Hardy"). By this reply, Applicant cancels claim 16, amends claims 1, 5, 14, 15, and 17, and addresses each of the Examiner's rejections below.

Support for the Amendments

Support for the amendments to claims 1, 5, and 17 is found in the specification on page 7, lines 12-21, page 10, lines 8-15, and Figures 3 and 4. Although the term "circumferential" is not present in the specification with respect to spiky projections of the cell membrane, as is presently recited in claims 1, 5, and 17, *ipsis verbis* disclosure is not necessary to satisfy the written description requirement of 35 U.S.C. § 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. Here, Figure 3 of the specification clearly shows that the SPR organism has spiky membrane projections that surround its circumference. Based on the evidence provided in Figure 3, one skilled in the art would reasonably conclude that the spiky membrane projections of the SPR organism are circumferential, and therefore, recitation of this term is not new matter (*In re Edwards*, 568 F.2d 1349, 1351-52, 196 U.S.P.Q. (BNA) 465, 467 (CCPA 1978).

Similarly, the term "behavior", present in amended claims 1, 5, and 17, is also not new matter. The specification clearly discloses that the SPR organism switches between a solitary living stage and a clustering stage "in which many organisms come together to form large colonies" (see, e.g., page 10, lines 8-15, of the specification). The skilled artisan would appreciate that the switch from a solitary living stage to a colonial clustering stage is a behavior

of the SPR organism that is modified according to, e.g., its living environment, access to nutrients, and reproductive needs. Therefore, recitation of this term is not new matter.

Support for the amendment to claims 14 and 15 is found in Fig. 1 and on page 9, lines 8-17, of the specification. Further support for the amendment to claim 14 is found in cancelled claim 16. No new matter is added by this amendment.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 1 and 19-21 are rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The rejected claims are directed to a biologically pure culture of a single-celled organism, termed "SPR" for spiky rotating cells, which Applicant has identified as being the causative agent in nongonococcal urethritis. The Examiner states:

> The claims are directed to a genus of single-cell organisms spiky rotating cells that have seven recited biological characteristics, but only a single species of SPR cell has been described. A single species does not describe the claimed highly variable genus of cells that may have any number of spiky membrane projections, and is a provisional protozoan. How additional species of the claimed genus would be similar or different from the single disclosed species of SPR has not been described. What has not been described, has not been enabled. (Office Action, pp. 6-7.)

Thus, the Examiner asserts that the instant specification fails to provide an adequate written description of the present invention within the full scope of the claims. Applicant respectfully traverses this rejection.

In order to fulfill the written description requirement of § 112, the patent specification does not need to describe exactly all the subject matter that is claimed. *In re Daniels*, 114 F.3d 1452, 46 U.S.P.Q.2d 1788 (Fed. Cir. 1998); *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 227 U.S.P.Q. 117 (Fed. Cir. 1985). Rather, the specification must clearly allow a person of

ordinary skill in the art to recognize that the inventor has invented what is claimed. *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998). In applying this standard, the Federal Circuit has held that the specification must convey with reasonable clarity to a skilled artisan that the inventor "was in possession of the invention" at the time of filing. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991).

Claim 1 has been amended to clarify the biological characteristics that distinguish the single-celled organism, SPR, over other prior art organisms, and now recites that the organism has "multiple circumferential spiky membrane projections of the cell membrane" and exhibits "periodic clustering behavior to form colonies." As is discussed below, these characteristics, in combination with the five other recited characteristics, are not associated with any other art-described organism and serve to clearly distinguish the presently claimed organism from these other organisms. Therefore, the skilled artisan can clearly distinguish an SPR organism from another organism, e.g., *Trichomonas vaginalis* or *Tritrichomonas foetus*, by using these characteristics.

The definition put forth in claims 1, 5, and 17 defines the essential characteristics of an SPR organism. The definition is based on the unique structural and behavioral features of this organism. These features distinguish an SPR organism from all other known protozoal organisms. The features recited in claims 1, 5, and 17 are necessary and sufficient for the identification of an SPR organism. They define the necessary conditions for identifying an SPR organism in that all of these characteristics must be present for an organism to be recognized as belonging to the taxon SPR. If an organism lacks any one of these characteristics, it is not an SPR organism.

Furthermore, this definition puts forth the sufficient conditions for the identification of an organism as belonging to the taxon SPR. Even though an organism may have additional features, as long as it exhibits the seven defining characteristics recited in claims 1, 5, and 17, it is an SPR organism. Therefore, additional species of the claimed genus are similar in so far as they have all of the seven defining characteristics of claims 1, 5, and 17.

The M.P.E.P. § 2163(II)(A)(3)(a)(ii) states that the written description requirement can be satisfied through sufficient disclosure of relevant, identifying characteristics of a claimed genus, which Applicant's specification clearly provides. Moreover, in *Regents of the University of California v. Eli Lilly & Co.,* the Federal Circuit acknowledged that "every species in a genus need not be described in order that a genus meets the written description requirement." 43 U.S.P.Q.2d at 1405 (citing *Utter v. Hiraga*, 845 F.2d 993, 6 U.S.P.Q2d 1709 (Fed. Cir. 1988) ("A specification may, within the meaning of § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.") Furthermore, "[d]escription of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces" (M.P.E.P. § 2163(II)(A)(3)(a)(ii)). Thus, the Examiner's argument that the SPR organism is the only species described in the specification is not sufficient to establish that the specification lacks an adequate written description for the claimed invention. To the contrary, it is not necessary for the specification to describe other species of SPR in order to satisfy the written description requirement since, as discussed above, the relevant identifying characteristics and biological properties of the organism has been provided. For this reason, Applicant respectfully submits that the instant specification provides an adequate written description of the claimed invention. The § 112 rejection should, therefore, be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 1, 5-7, 9-12, 16, 17, 19-21, and 36-37 are rejected under 35 U.S.C. § 112, second paragraph, for lack of clarity. The Examiner states that the phrase "periodic colonial clustering" recited in claims 1, 5-7, 9-10, 12, 17, 19-21, and 36-37, "is not an art recognized phrase to describe a specific phenotypic or genotypic biological or chemical characteristic of bacterial or protozoan growth...The phrase 'periodic colonial clustering' does not distinctly claim Applicant's invention." (Office Action, p. 7).

Claims 1, 5, and 17 have been amended to recite "periodic clustering behavior to form colonies," which reflects that the periodic clustering to form colonies occurs as a deliberate action of the SPR organism and is not simply an artifact of laboratory manipulation as occurs due to streaking of an organism, such as a bacterium, on an agar plate. The term "periodic clustering behavior" does not define the result of a "standardized" protocol (e.g., a growth pattern that results from streaking an organism on a growth medium-containing petri dish), but rather, a characteristic behavior (i.e., clustering) of the SPR organism that occurs over time (i.e., periodically). The present amendment to claims 1, 5, and 17 clarifies this issue, and therefore, the rejection of claims 1, 5-7, 9-10, 12, 17, 19-21, and 36-37 under 35 U.S.C. § 112, second paragraph, for lack of clarity should be withdrawn.

The Examiner also states that claim 16 depends from itself and therefore is unclear. Applicant has cancelled claim 16. Therefore, this rejection should now be withdrawn as well.

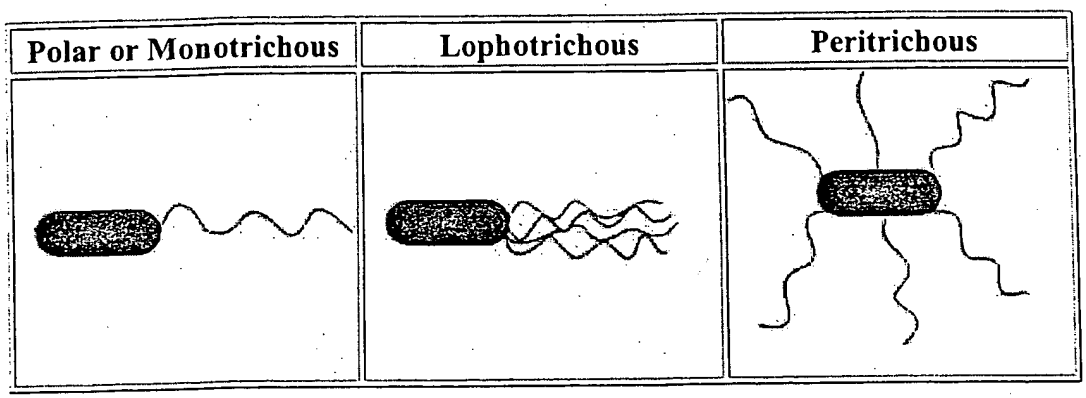
Rejections Under 35 U.S.C. § 102(b)

Abou El Seoud

Claims 1, 5, 7, 10, 12, and 19-21 are rejected under 35 U.S.C. § 102(b) for anticipation by Abou El Seoud. The Examiner states that although the phrase "periodic colonial clustering" has been used to define a functional characteristic and patentable novelty of the claimed composition, "this phrase is not an art recognized phrase to describe bacterial or protozoan growth" (Office Action, p. 4). Furthermore, isolates of the protozoan of Abou El Seoud would periodically produce colonies when prepared using the art-known technique of streaking an organism onto a selective growth-medium-containing petri dish. Therefore, "Applicant's arguments have not distinguished the claimed invention from the applied prior art" (Office Action, p. 4). Applicant respectfully disagrees, but has amended claim 1 to recite "periodic clustering behavior to form colonies," which clarifies that the periodic colonial clustering exhibited by the SPR organism is behavior-driven and not simply due to experimental manipulation.

As is discussed above, the specification clearly teaches that the SPR organism periodically undergoes a switch from a solitary single-celled organism to a communal clustering organism. When this behavioral change occurs, the SPR organism actually moves itself toward other SPR organisms to form clusters of several cells. In contrast, *Trichomonas vaginalis,* which is described by Abou El Seoud, is not know to form clusters of cells due to a *behavior* of the organism, nor is this an inherent behavioral property of *T. vaginalis*. Although *T. vaginalis* may form clusters of cells when applied to a petri dish and cultured, this is merely an artifact of the biological technique; the cell clusters would not result from a behavioral shift of the organism from a solitary stage to a communal stage, as occurs with the SPR organism of present claim 1. For this reason, the organism of present claim 1 is not taught or suggested by Abou El Seoud.

In addition, *T. vaginalis* is a flagellated protozoan. Flagella are rigid structures made up of microtubules that rotate like a propeller. They are designed to move the cell itself or to move substances over or around the cell. The diameter of a flagellum is ~20 nm wide and a length 10 times the diameter of cell (about 100 nm). The figure below demonstrates some of the more common flagellar arrangements.



In contrast to *T. vaginalis*, the organism of present claim 1 does not possess flagella, but rather "multiple *circumferential* spiky membrane projections of the cell membrane," as is now recited in present claim 1. These deformations are not present in *T. vaginalis*. For this reason as well, the organism of present claim 1 is not taught or suggested by Abou El Seoud. Because Abou El Seoud fails to teach or suggest an organism that satisfies all of the limitations of present claim 1, and claims dependent therefrom, or a method of diagnosing an organism, as is recited in claim 5, and claims dependent therefrom, Applicant respectfully requests that the rejection of claims 1, 5, 7, 10, 12, and 19-21 under 35 U.S.C. § 102(b) over Abou El Seoud be withdrawn.

Monteiro-Leal

The Examiner also rejects claims 1 and 19-21 under 35 U.S.C. § 102(b) for anticipation by Monteiro-Leal. The Examiner states that "Monteiro-Leal et al. disclose a biologically pure

culture of a single celled organism (see Figure 1, page 207), that was cultured to produce a large colony of the protozoan" (Office Action, p. 5). Applicant respectfully disagrees.

Applicant first points out that Monteiro-Leal describes *Tritrichomonas foetus*, which is a pathogen of cattle, not humans (see, e.g., p. 206 of Monteiro-Leal). Therefore, *T. foetus* is not an "organism that causes disease in humans", as is recited in present claim 1, and claims dependent therefrom. Second, as is discussed above, claim 1 has been amended to recite that the SPR organism exhibits "periodic clustering behavior to form colonies" and "multiple circumferential spiky membrane projections." *Tritrichomonas foetus*, which is described by Monteiro-Leal, does not exhibit either of these biological characteristics. As is clearly described by Monteiro-Leal, *T. foetus* have three anterior flagella and one undulating membrane formed by the association of the recurrent flagellum and part of the cell surface (Figure 1, Monteiro-Leal). The SPR organism of present claim 1, and claims dependent therefrom, does not possess a flagellum, but rather, multiple circumferential spiky membrane projections. Figure 1 of Monteiro-Leal clearly indicates that *T. foetus* does not exhibit multiple circumferential spiky membrane projections. Furthermore, contrary to the Examiner's assertion, Monteiro-Leal fails to teach or suggest that *T. foetus* exhibits any clustering behavior, much less periodic clustering behavior, as is presently recited in claim 1. Monteiro-Leal merely states that "[t]he K strain of *T. foetus* was cultivated in TYM medium for 36 h at 37°C" (p. 207 of Monteiro-Leal). This passage, while indicating that *T. foetus* likely multiplied (i.e., "was cultivated"), fails to indicate that individual cells of *T. foetus* came together to form a cluster or that this characteristic was observed or used by Monteiro-Leal as a distinguishing biological characteristic for identification or diagnosis of the organism. For these reasons, Monteiro-Leal fails to teach or suggest an organism that satisfies all of the limitations of present claim 1, and claims dependent therefrom, or a method of diagnosing

an organism, as is recited in claim 5, and claims dependent therefrom. Therefore, Applicant respectfully requests that the rejection of claims 1 and 19-21 under 35 U.S.C. § 102(b) over Monteiro-Leal be withdrawn.

Andrews

The Examiner also rejects claims 5 and 10 under 35 U.S.C. § 102(b) for anticipation by Andrews. The Examiner states:

> Andrews does carry out the method steps of obtaining a sample from a patient, wherein the sample...is a human sample...[and] testing for the presence of a single celled organism that is spiky and rotating (motile protozoan)...The SPR infection causing pathogen diagnosed by Andrews et al, is a protozoan, the protozoan evidencing the recited characteristics. (Office Action, p. 5.)

Applicant respectfully disagrees.

The M.P.E.P. § 2131 states that "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." As was discussed in the previous Reply to Office Action, filed with the Request for Continued Examination on April 4, 2004, Andrews fails to disclose a method for diagnosing an organism that exhibits all of the biological and morphological characteristics recited in present claim 5 (e.g., disease in humans, periodic clustering behavior to form colonies, and multiple circumferential spiky projections of the cell membrane). Andrews merely describes a method of treating *Entamoeba histolytica*, *Trichomonas vaginalis*, *Giardia lamblia*, *Cryptosporidium parvum*, *Tritrichomonas foetus*, and *Tritrichomonas gallinae*; organisms which do not exhibit all of the limitations of present claim 5.

T. foetus and *T. gallinae* are animal pathogens that do not cause disease in humans. Therefore, these organisms do not meet the limitations of present claim 1. *G. lamblia* and *T. vaginalis* also do not meet the limitations of present claim 1 because they both possess flagellum rather than multiple circumferential spiky membrane projections (see above for discussion of *T. vaginalis*). Furthermore, neither *G. lamblia* or *T. vaginalis* exhibit periodic clustering behavior to form colonies, as is now required by claim 5. Finally, *C. parvum* also does not exhibit all of the biological characteristics recited in present claim 5, because it lacks "a spherical shape measuring approximately 7-8 μm in diameter." On the contrary, *C. parvum* is a small parasite measuring 3-5 μm in diameter. Further, *C. parvum* does not exhibit either periodic clustering behavior to form colonies or circumferential spiky membrane projections.

Because none of the organisms described by Andrews exhibits all of the characteristics of the organism recited in present claim 5, the method of Andrews would fail to enable one skilled in the art to diagnose an SPR infection. For this reason, the rejection of claims 5 and 10 under 35 U.S.C. § 102(b) over Andrews should be withdrawn.

Birthistle

Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Birthistle. The Examiner states:

> ...Birthistle and Larson both diagnose a disease in a patient that [sic] are caused by a SPR (Monteiro-Leal and El-Seoud provide evidence of protozoan species that meet the functional limitations recited in the claims, and the organisms treated by [sic] Bisthistle and Larson are protozoan organisms), wherein the patient may be a mammal, specifically a human. (Office Action, p. 6.)

Applicant respectfully disagrees.

Birthistle discloses treating a patient diagnosed with urethritis associated with microsporidia. Microsporidia is an intracellular protozoan parasite. Claim 17 is directed to a method of treating an SPR infection by first diagnosing an SPR infection, which is performed by, *inter alia*, detecting an extracellular organism. The SPR organism is also identified by multiple circumferential spiky membrane projections and its periodic clustering behavior to form colonies, as is now recited in claim 17. Microsporidia exhibit none of these characteristics. Because Birthistle fails to teach or suggest a method that includes diagnosing an SPR infection based on the identification of an organism that exhibits all of the recited biological characteristics of claim 17, Birthistle fails to teach or suggest all of the limitations of claim 17, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 102(b) over Birthistle be withdrawn.

Larson

Claim 17 is rejected under 35 U.S.C. § 102(b) for anticipation by Larson. The Examiner states that Larson discloses diagnosing a disease in a patient that is caused by an SPR organism. Applicant respectfully disagrees.

The Examiner points to col. 6, lines 32-37, of Larson for evidence that Larson discloses treating a mammal. This passage of Larson merely states that "[i]n preferred embodiments, the suspensions of the present invention may be made into an injectable syringeable form and administered to the mammal by parenteral administration. The mammal may be a bovine, an equine, a porcine, a canine, a feline, or any mammal" (col. 6, lines 32-37). In previous Office Actions, the Examiner has pointed to claims 33-41 of Larson for evidence of the diagnostic and treatment steps of claim 17. Claims 33-41 of Larson merely discloses a method for treating an

infection caused by, e.g., a protozoan, by administering microcrystals containing an antibiotic encapsulated by a phospholipid layer (see, e.g., claims 33 and 41 of Larson). Larson clearly fails to teach or suggest a diagnostic step which requires detecting an organism that exhibits all of the biological characteristics recited in claim 17. For this reason, Larson fails to teach or suggest all of the limitations of claim 17, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that the rejection of claim 17 under 35 U.S.C. § 102(b) over Larson be withdrawn.

Van der Schee

Claims 5, 7, 9, 10, 19, 20-21, and 36-37 are rejected under 35 U.S.C. § 102(b) for anticipation by Van der Schee. The Examiner argues that Van der Schee discloses all of the elements of present claims 5, 7, 9, 10, 19, 20-21, and 36-37. Applicant respectfully disagrees.

Applicant notes that although claim 19 was included in the rejected claims recited in the Office Action, it is dependent on claim 1, which is not rejected over Van der Schee. Therefore, Applicant believes that the inclusion of claim 19 in the rejection is an error and has not addressed its patentability with respect to this reference.

Van der Schee discloses an improved method for diagnosing *T. vaginalis* using PCR. Van der Schee fails to disclose any additional diagnostic steps that include identifying an organism that exhibits multiple circumferential spiky projections of the cell membrane and periodic clustering behavior. As is discussed above, *T. vaginalis* does not exhibit these characteristics and is distinct from the SPR organism based on the biological characteristics recited in present claim 5 (see discussion of Abou El Seoud above). Therefore, the method of Van der Schee, which fails to employ all of the steps of present claim 5, and claims dependent

therefrom, would fail to identify an SPR organism and, consequently, diagnose an SPR infection. For this reason, Van der Schee fails to teach or suggest all of the limitations of claims 5, 7, 9, 10, 20-21, and 36-37, as is required (see M.P.E.P. § 2131, *supra*). Therefore, Applicant respectfully requests that this rejection be withdrawn.

Kritzman

Claims 5 and 6 are rejected under 35 U.S.C. § 102(b) for anticipation by Kritzman. The Examiner states that Kritzman discloses obtaining a sample from a patient and testing the pH of the sample for the presence of *T. vaginalis*, and that this disclosure anticipates the claimed invention. Applicant respectfully disagrees.

Kritzman describes a method for determining the presence of a pathological state in a person, e.g., bacterial vaginosis, by automatically analyzing bodily secretions, e.g., vaginal secretions, collected in a device (i.e., an absorbent pad) worn by the person (see, e.g., col. 3, lines 56-67 and col. 8, lines 53-67). Diagnosis of a pathological condition using the Kritzman device occurs by observing a change in the color of the absorbent pad of the device due to an increase in the pH of a bodily secretion of the user. The absorbent pad is further analyzed biochemically using, e.g., PCR, LCR, RT-PCR, immunoassay, ELISA, RIA, FACS, gel electrophoresis, microscopy, immuno-fluorescence, SNIRPS analysis, and/or restriction fragment length polymorphism (RFLP) analysis to confirm the diagnosis (see col. 9, lines 23-40). None of these detection methods, with the exception of microscopy, allows testing a sample for the presence of an organism by detecting an organism with all of the biological characteristics recited in present claim 5. Although microscopy could be used to detect infection of a person by an SPR organism, Kritzman fails to teach or suggest how one would use microscopy to detect an SPR organism.

For this reason, Kritzman fails to teach or suggest all of the limitations of present claims 5 and 6. Accordingly, Applicant respectfully requests that the rejection of claims 5 and 6 under 35 U.S.C. § 102(b) for anticipation by Kritzman be withdrawn.

Bush

Claim 14 is rejected under 35 U.S.C. § 102(b) for anticipation by Bush. The Examiner states that "Bush et al disclose the instantly claimed invention directed to an instrument that comprises: a handle...and a means that comprises a loop region" (Office Action, p. 8). Applicant has amended claim 14 to recite that the device additionally comprises a pH sensor positioned adjacent the collecting means. Bush fails to teach or suggest a device that comprises a handle portion, a collecting means comprising a loop region, and a pH sensor. Because Bush fails to teach or suggest all of the elements of claim 14, as presently amended, Applicant respectfully requests that the rejection of claim 14 under 35 U.S.C. § 102(b) for anticipation by Bush be withdrawn.

Nucci

Claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Nucci. The Examiner states that Nucci discloses an instrument that has both a handle portion, a means for collecting a secretion sample of a female patient, and a pH indicator, and therefore, Nucci anticipates the invention of claim 15. Applicant respectfully disagrees.

Nucci discloses a disposable probe that is designed as "a small pipe with a closed head, a hole provided near the head and one or more pH indicators or other indicators disposed within the probe" (Abstract). The Nucci device functions by collecting vaginal liquid that enters

through the oval hole of the device and flows from the head to the opposite end upon introduction of the device into the vagina (see col. 2, lines 52-59). Contact of the vaginal secretion with the indicator allows determination of the pH of the sample.

In contrast to the Nucci device, which contains a collecting means (the oval hole) *near* the end of the head of the device, the collecting means (i.e., the loop region) of the device of present claim 15, as amended, is positioned at the *end* of the device opposite the handle portion (see also Figure 1 of Applicant's specification). Furthermore, the Nucci device cannot be used to collect a vaginal sample or detect its pH under conditions in which the vagina is dry because it requires that the vaginal liquid flows into the device so that it can come into contact with the indicator. The device of present claim 15, on the other hand, can be used to obtain a vaginal sample and detect the pH of that sample even under dry conditions because the device can be used to scrape the vaginal mucosa, if necessary, to obtain the sample and because the pH indicator is located so that it comes into direct contact with the vaginal mucosa upon insertion of the device into the vagina. The pH indicator of the Nucci device is positioned inside a pipe and never comes into direct contact with the vaginal mucosal. For all of the reasons provided above, Nucci fails to teach or suggest all of the elements of present claim 15. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

Hardy

Claim 15 is rejected under 35 U.S.C. § 102(b) for anticipation by Hardy. The Examiner states that Hardy anticipates claim 15 by disclosing an instrument for collecting a sample from a female patient, in which the instrument comprises a handle portion and a means for collecting the

secretion, which includes a loop region with an opening and one or more indicators for pH determination. Applicant respectfully disagrees.

Hardy describes an instrument for testing pH values of body canal liquids. The handle portion of Hardy's instrument includes a loop region with an opening positioned at the handle portion, presumably to allow the user to grasp the device by inserting a finger through the hole (see Figures 1 and 2, and col. 2, lines 1-4). In contrast, the loop region of the device of present claim 15 is the collecting means of the device and is separated from the handle portion of the device by being positioned at the end of the device opposite the handle portion. Therefore, rather than serving as a means to grasp the device, as is disclosed in Hardy, the loop region of the device of claim 15 is the collecting means of the device and is inserted into the vagina of a subject. Accordingly, the Hardy device is structurally distinct from the device of present claim 15. For this reason, Applicant respectfully requests that the rejection of claim 15 for anticipation over Hardy be withdrawn.

CONCLUSION

Applicant submits that the claims are now in condition for allowance, and such action is respectfully requested.

Enclosed is a petition to extend the period for replying for three months, to and including April 29, 2004, and a check for the fee required under 37 C.F.R. § 1.17(a).

If there are any charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: April 29, 2004

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